ointment into a separatory funnel containing 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous, add 20–25 milliliters of 0.1 *M* potassium phosphate buffer, pH 8.0 (solution 3), and shake well. Allow the layers to separate. Remove the buffer layer and repeat the extraction with new portions of the buffer and repeat any additional times necessary to insure complete extraction of the antibiotic. Combine the extractives and adjust to an appropriate volume to give a stock solution of convenient concentration. Further dilute with solution 3 to the reference concentration of 0.1 microgram of gentamicin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

[39 FR 19046, May 30, 1974, as amended at 50 FR 19919, May 13, 1985]

§ 444.520b Gentamicin sulfate cream.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Gentamicin sulfate cream is gentamicin sulfate with one or more suitable emollients, dispersants, and preservatives in a suitable and harmless cream base. Each gram contains gentamicin sulfate equivalent to 1.0 milligram of gentamicin. Its potency is satisfactory if it is not less than 90 percent and not more than 135 percent of the number of milligrams of gentamicin that it is represented to contain. The gentamicin sulfate used conforms to the standards prescribed therefor by § 444.20(a)(1).

(2) *Packaging.* In addition to the requirements of § 432.1 of this chapter, it may be dispensed from a pressurized container wherein it is maintained in a compartment separate from the gas used to supply the pressure.

(3) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(4) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The gentamicin sulfate used in making the batch for potency, loss on drying, pH, specific rotation, gentamicins C_1, C_{1a}, and C_2, and identity.

(*b*) The batch for gentamicin potency.

(ii) Samples required:

(*a*) The gentamicin sulfate used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay; potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the cream into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 0.1*M* potassium phosphate buffer, ph 8.0 (solution 3), and shake gently to avoid gel formation. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20 to 25 milliliter quantities of solution 3. Combine the buffer extractives and adjust to an appropriate volume to obtain a stock solution of convenient concentration. Further dilute with solution 3 to the reference concentration of 0.1 microgram of gentamicin per milliliter (estimated).

[39 FR 19046, May 30, 1974, as amended at 46 FR 45332, Sept. 11, 1981; 50 FR 19919, May 13, 1985]

§ 444.540 Neomycin palmitate dermatologic dosage forms.

§ 444.542 Neomycin sulfate dermatologic dosage forms.

§ 444.542a Neomycin sulfate ointment; neomycin sulfate- ———— ointment (the blank being filled in with the established name(s) of the other active ingredient(s) present in accordance with paragraph (a)(1) of this section).

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Neomycin sulfate ointment contains, in each gram, 3.5 milligrams of neomycin in a suitable and harmless water-soluble or oleaginous ointment base, with or without one or more suitable and harmless dispersants, emollients, and preservatives. The following other drugs may be combined with neomycin sulfate ointment in the indicated amounts, per gram: